August 26, 2026

Boston Scientific Corporation
Avinash Purohit
Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K261153
Trade/Device Name: LithoVue Elite Digital Flexible Ureteroscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: July 24, 2026
Received: July 24, 2026

Dear Avinash Purohit:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: The Center for Devices and Radiological Health (CDRH) does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

The FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), ["*Attachment AI-1 - Revised PCCP for AI Response.pdf*," Rev 02]. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a

device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MARK J. ANTONINO -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261153

Device Name
LithoVue Elite Digital Flexible Ureteroscope System

Indications for Use *(Describe)*
The LithoVue Elite Digital Flexible Ureteroscope System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary for LithoVue Elite Digital Flexible Ureteroscope System

Date Prepared: 19-August-2026

A. Submitter

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Urology Division
100 Boston Scientific Way
Marlborough, MA 01752

B. Contacts

Avinash Purohit
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C. Device Names

Trade Name(s):	**LithoVue™ Elite Digital Flexible Ureteroscope System**
Common/Usual Name:	Ureteroscope and Accessories, Flexible/Rigid
Regulation Number:	21 CFR §876.1500
Regulation Name:	Endoscope and accessories
Classification:	Class II
Product Code:	FGB

D. Predicate and Reference Devices

For the purpose of establishing 'substantial equivalence', the design and technological characteristics of the proposed LithoVue Elite Digital Flexible Ureteroscope system were compared to the following 510(k)-cleared devices.

Predicate and Reference Device for Establishing 'Substantial Equivalence'

	Predicate Device	Reference Device
Device Trade Name(s):	LithoVue Elite Digital Flexible Ureteroscope System	LithoVue™ Elite Single-Use Digital Flexible Ureteroscope (with Pressure Monitoring)
Regulation Name:	Endoscope and accessories	Endoscope and accessories
Regulation Number:	21 CFR §876.1500	21 CFR §876.1500
Classification:	Class II	Class II
Product Code:	FGB	FGB
510(k) Submitter/Holder:	Boston Scientific Corporation Marlborough, MA 01752	Boston Scientific Corporation Marlborough, MA 01752
510(k) #/ Clearance Date	K233645 12-December-2023	K252703 24-September-2025

E. Device Description

The LithoVue Elite Digital Flexible Ureteroscope System is a software-controlled digital flexible ureteroscope system that consists of the *StoneSmart Connect Console* and the *Single-Use Digital Flexible Ureteroscopes (with and without pressure monitoring capability)*. The LithoVue Elite Digital Flexible Ureteroscope System is designed to allow the physician to access, visualize and perform procedures in the urinary tract.

The devices within the scope of this Traditional 510(k) premarket notification are: StoneSmart Connect Console and LithoVue Elite Single-Use Digital Flexible Ureteroscope with Pressure Monitoring.

The software update to the console enables real-time temperature monitoring of fluid near the distal tip of ureteroscope during ureteroscopy procedures. The functionality is achieved by leveraging the inherent capabilities of the existing piezoresistive MEMS pressure sensor located at the distal tip of ureteroscope. This allows the end user with the ability to view real-time fluid temperature readings on a connected external display during urology procedures.

The temperature value presented to the user onscreen represents the temperature of the intraluminal fluid at the distal tip end of the ureteroscope. These readings do not represent core body temperature.

Additionally, modification to the ureteroscope enables the StoneSmart Connect Console to distinguish between a ureteroscope that supports and does not support temperature monitoring. The console activates the temperature monitoring feature only when a compatible ureteroscope is connected.

F. Intended Use/Indications for Use

The indications for use of the LithoVue Elite Digital Flexible Ureteroscope System cleared with predicate device remains valid. Therefore, no change to the cleared indications for use (presented below) is proposed in the current submission.

The LithoVue Elite Digital Flexible Ureteroscope System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

G. Operating Principle

The operating principles for illumination and intraluminal pressure monitoring are unchanged from those of the predicate device and continue to apply to the proposed devices.

- The illumination is generated by an LED located in the ureteroscope handle and transmitted to the distal tip lens via a fiber-optic illumination fiber. A digital CMOS imager located in the distal tip of the ureteroscope provides the raw image data from the surgical field. The raw image data is transferred from the CMOS imager through the ureteroscope handle, via the umbilicus, to the console for processing and output to an external display.

- The console supports real-time intraluminal pressure monitoring when used with a ureteroscope with pressure monitoring capability. The ureteroscope contains a Micro-Electro-Mechanical Systems (MEMS) piezoresistive pressure sensor located at the distal tip of the ureteroscope. Pressure signals from the ureteroscope are transmitted to the console for real-time display of the pressure value on an external display.

Temperature monitoring leverages the inherent functionality of the existing piezoresistive MEMS pressure sensor located at the distal tip of ureteroscope to enable real-time display of fluid temperature at that location. Signals from the ureteroscope are transmitted to the console for real-time display of the temperature value on an external display.

H. Comparison of Key Technological/Performance Characteristics

The proposed LithoVue Elite Digital Flexible Ureteroscope System ("LithoVue Elite System") has the same technological characteristics and fundamental design as the predicate device per **Table 12-1**.

Table 12-1: Technical Specifications Comparison

Feature	Proposed LithoVue Elite System	Predicate LithoVue Elite System (K233645)	Substantial Equivalence Discussion
General			
Reusability	Ureteroscope: Single Use Console: Reusable	Ureteroscope: Single Use Console: Reusable	Identical
Ureteroscope Type	Flexible	Flexible	Identical
Ureteroscope is Supplied	Sterile	Sterile	Identical
Sterilization Agent	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Identical
Imager Type	CMOS	CMOS	Identical
Illumination Source	LED	LED	Identical
Ureteroscope Mechanical Specifications			
Shaft Working Length	68 cm	68 cm	Identical
Shaft OD	9.5F	9.5F	Identical
Insertion Portion Width (Distal Face)	7.7F	7.7F	Identical
Working Channel Size	3.6F (1.15mm MIN ABS)	3.6F (1.15mm MIN ABS)	Identical
Working Length	82 cm	82 cm	Identical
Deflection	Active and Passive	Active and Passive	Identical
Degree of Active Deflection	270° in both directions	270° in both directions	Identical
Optical Specifications			
Field of View (in air)	120° diagonal in air	120° diagonal in air	Identical

Feature	Proposed LithoVue Elite System	Predicate LithoVue Elite System (K233645)	Substantial Equivalence Discussion
Working Distance	2 - 50 mm	2 - 50 mm	Identical
Direction of View	0° (forward viewing)	0° (forward viewing)	Identical
Resolution[1]	Typical (5mm Distance): >9.81 lp/mm	Typical (5mm Distance): >9.81 lp/mm	Identical
Image Processing			
Image Processing	Performed by console	Performed by console	Identical
White Balancing	Not required – white balancing is set at factory	Not required – white balancing is set at factory	Identical
Brightness Control	Adjustable on console GUI	Adjustable on console GUI	Identical
Pressure Measurement			
Pressure Measurement Accuracy (Applies to ureteroscope with pressure monitoring only)	Procedure Duration Post Initialization: **0 minutes to 60 minutes:** 0 mmHg - 100 mmHg: (+/- 10 mmHg) 100 mmHg - 300 mmHg: (+/- 5 mmHg + 5 % of reading) **60 minutes to 120 minutes:** 0 mmHg - 100 mmHg: (+/- 13 mmHg) 100 mmHg - 300 mmHg: (+/- 8 mmHg + 5 % of reading)	Procedure Duration Post Initialization: **0 minutes to 60 minutes:** 0 mmHg - 100 mmHg: (+/- 10 mmHg) 100 mmHg - 300 mmHg: (+/- 5 mmHg + 5 % of reading) **60 minutes to 120 minutes:** 0 mmHg - 100 mmHg: (+/- 13 mmHg) 100 mmHg - 300 mmHg: (+/- 8 mmHg + 5 % of reading)	Identical

[1]per 1951 USAF resolution test chart

The direct and indirect patient-contacting materials remain identical between the proposed ureteroscope with pressure monitoring and reference ureteroscope (K252703). The main difference between the predicate and proposed devices is the capability to measure the temperature of fluid at the distal tip of the ureteroscope during ureteroscopy procedures. The capability provides the physician with a real-time temperature measurement (reading) at the anatomical site, rather than the current standard of care which relies on using indirect and subjective methods, such as manually feeling the temperature of inflow tubing or outflow fluid. Temperature monitoring leverages the inherent capabilities of the existing piezoresistive MEMS pressure sensor located at the distal tip of ureteroscope to measure the fluid temperature within the anatomy during ureteroscopy.

I. Substantial Equivalence

A comprehensive comparison of the proposed LithoVue Elite System to the predicate and reference devices, including indications for use, technological characteristics (e.g., design, materials, and performance specifications), and operating principles support the determination of substantial equivalence. The differences between the proposed and predicate devices do not alter the suitability of the proposed LithoVue Elite System for its intended use.

J. Performance Testing

Design verification (bench) testing was conducted to evaluate the modifications implemented to enable the temperature monitoring capability. Verification activities were performed to confirm that the temperature monitoring functionality performs as intended and meets established design specifications.

Usability and Human Factors engineering activities were conducted in accordance with applicable FDA guidance and included preliminary analyses and evaluations, identification of critical tasks, and summative validation testing. The results support the conclusion that the LithoVue Elite System with the proposed temperature monitoring capability remains safe and effective for its intended users, intended uses, and use environments.

Software and Cybersecurity testing was completed for this submission. The software documentation stipulated in FDA guidance document, Content of Premarket Submissions for Device Software Functions (issued June 14, 2023) was included in this premarket submission. The Cybersecurity assessment was conducted to assess compliance with FDA guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” (issued February 2026).

K. Predetermined Change Control Plan (PCCP):

The predetermined change control plan (PCCP) for the device specifies anticipated modifications to 1.) ureteroscope design, which consists of a refined illumination configuration, as well as changes to components and patient-contacting materials to support continued device performance and manufacturability 2.) console software updates in support of the illumination change. The PCCP also specifies the methods to implement those modifications so that the device remains as safe and as effective as the predicate device. The detailed description of the modifications, testing methods, validation activities, performance requirements, and communication to users are summarized in the table below.

Planned Modifications	**Test Methods and Validation Activities**	**Communication to user, as needed**
Ureteroscope design: • Refined illumination configuration • Updated articulation section and outer jacket • Change to electrical grounding connection and handle electronics, and molded components	• Bench testing will be performed to ensure the modified device meets applicable specifications. • Electrical & EMC testing will be repeated. In consideration of the changes to device, applicable clauses of the following FDA-recognized voluntary consensus standards will be re-tested: o IEC 60601-1, Edition 3.2 o IEC 60601-1-2, Edition 4.1 Testing will follow the recommendation of FDA Guidance, “Electromagnetic Compatibility (EMC) of Medical Devices”. • Usability and Human Factors Engineering activities will be performed in accordance with FDA guidance, “Applying Human Factors and Usability Engineering to Medical Devices” • Biocompatibility will be evaluated according to FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and ISO 10993-1:2018 for the body contact category of “Externally Communicating – Tissue/Bone/Dentin” with a contact duration of “Limited (≤24 hours). • Sterilization qualification and EO residual verification will be repeated using the modified device. Evaluations will be	Modified devices will be identifiable through a new differentiator as well as new catalog number. Labeling will be updated in accordance with the authorized PCCP.

	conducted per the following consensus standards: o ISO 11135, Second Edition 2014-07-15 o ISO 10993-7:2008/A1:2022 All the aforementioned testing will be conducted as per the plan in modification protocol submitted with PCCP.	
Console software updates to support the illumination configuration change	• Software testing will be conducted as per the submitted software test plan in the modification protocol of the authorized PCCP.	Labeling will be updated in accordance with the authorized PCCP.

L. Conclusion

Based on the intended use/indications for use, comparison of key technological characteristics, and performance testing presented in this premarket notification, it is concluded that the proposed LithoVue Elite System is substantially equivalent to the predicate.